K063844

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

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MAR 15 2007

Date Prepared: December 22, 2006

Trade Name: Reprocessed Heart Stabilizers and Positioners

Classification Name: Cardiovascular Surgical Instruments

Classification Number: Class I, 21 CFR 870.4500

Product Code: NQG

Predicate Devices:	The reprocessed heart stabilizers and positioners are substantially equivalent to the Medtronic Octopus Tissue Stabilizer (and positioner) (K964445). The non-reprocessed heart stabilizers and positioners are Class I, 510(k) exempt devices.
Device Description:	**Heart Stabilizers** are retractor-based devices that consist of two tissue stabilizers attached to an articulating arm. The ends of the tissue stabilizers are spaced about 8 to 15 mm apart, nominally. The articulating arm fastens to a retractor by use of a mounting clamp. The arm is tightened and loosened by a large knob on the proximal end. As the arm tightens, the tissue stabilizers spread a minimum of 3 mm in an arc fashion. Each slightly curved tissue stabilizer is composed of four suction pods. With the pods placed on either side of the anastamosis site, suction is applied to stabilize the tissue. A stopcock provides control of suction. **Heart Positioners** are designed to be used in conjunction with the Tissue Stabilizer to facilitate access to and enhance exposure of the coronary arteries for coronary artery bypass procedures. The device is retractor-based and incorporates a silicone suction apparatus, an articulating arm and a mounting clamp. The silicone apparatus is attached to the surface of the heart by the application of regulated vacuum. The mounting clamp has been designed to be compatible with most adult median sternotomy retractors.
Intended Use:	Heart Stabilizers and Positioners are devices that are designed to stabilize, move, lift, and position the heart during cardiovascular surgery.
Functional and Safety Testing:	Representative samples of reprocessed heart stabilizers and positioners underwent functional testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:	The reprocessed heart stabilizers and positioners are substantially equivalent to the Octopus Tissue Stabilizer (and Positioner) (K964445) manufactured by Medtronic. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2007

SterilMed Inc.
c/o Mr. Dennis Toussaint
Director of Regulatory Affairs
11400 73rd Avenue North
Maple Grove, MN 55369

Re: K063844
Octopus 3.0, 4.0, and 4.3 Stabilizers, Starfish 2 Positioner, and Urchin Positioner
Regulation Number: 21 CFR 870.4500
Regulation Name: Cardiovascular Surgical Instruments
Regulatory Class: Class I
Product Code: NQG
Dated: February 23, 2007
Received: February 26, 2007

Dear Mr. Toussaint:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063844

Device Name: Reprocessed Heart Stabilizers and Positioners

Indications For Use:
Heart Stabilizers and Positioners are devices that are designed to stabilize, move, lift, and position the heart during cardiovascular surgery. Tissue Stabilizers are designed to stabilize and minimize the movement of localized areas of a beating heart during off-pump cardiac surgery. Tissue Positioners are designed to lift and hold the heart in position during cardiac surgery.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063844

ProCode	Family	Model
NQG	Medtronic Heart Stabilizers and Positioners	Octopus 3.0 Stabilizer
		Octopus 4.0 Stabilizer
		Octopus 4.3 Stabilizer
		Starfish 2 Positioner
		Urchin Positioner